UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK
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GERARD FRANZESE and ROSEMARY FRANZESE,

Plaintiffs,

MEMORANDUM & ORDER
13-CV-3203(JS)(WDW)

-against-

ST. JUDE MEDICAL, INC. and ST. JUDGE MEDICAL S.C., INC.,

Defendants.
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APPEARANCES

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SEYBERT, District Judge:

Currently pending before the Court are: (1) defendants St. Jude Medical, Inc. and St. Jude Medical S.C., Inc. (together, "Defendants" or "St. Jude") motion to dismiss the Amended Complaint (Docket Entry 16), and (2) Defendants' motion to compel judicial notice (Docket Entry 17). For the following reasons, Defendants' motions are GRANTED.

BACKGROUND[1]

On April 14, 2010, plaintiff Gerard Franzese received surgery at St. Catherine of Siena Hospital on Long Island, New York to implant a St. Jude implantable defibrillator ("ICD")[2]. (Am. Compl. ¶ 19; see also Dell Aff., Docket Entry 23, ¶ 3.) During that procedure, a St. Jude representative was present and directing the procedure. (Am. Compl. ¶ 20.) The ICD that Mr. Franzese received was ICD Model Number CD3211-36Q; RV lead Model Number 7121Q/65, which used a Durata SJ4 RV lead (7121Q/65). (Am. Compl. ¶ 19.) Defendants designed, manufactured, assembled, tested, inspected, produced, marketed, imported, distributed, marketed and sold the defibrillator and the Durata lead. (Am. Compl. ¶ 12.)

Thereafter, the Durata lead wore away and prematurely deteriorated. (Am. Compl. ¶¶ 21-22.) On October 17, 2011, Mr. Franzese underwent a second ICD surgical procedure during which the lead was discarded and replaced. (Am. Compl. ¶ 25; Dell Aff. ¶ 8.) The second procedure was unsuccessful, thus causing a third surgery on October 28, 2011. (Am. Compl. ¶¶ 26-27.) A St. Jude representative informed Mr. Franzese that some of the

[1] The following facts are taken from Plaintiffs' Amended Complaint and are presumed to be true for the purposes of this Memorandum and Order.

[2] "ICD's are designed to be implanted near a patient's heart, monitor the heart rhythms and give life-saving electrical shocks if necessary." (Dell Aff. ¶ 6.)

St. Jude's leads were defective, including the lead he received on April 14, 2010. (Am. Compl. ¶¶ 29-30.)

Mr. Franzese and his wife Rosemary Franzese (together "Plaintiffs") raise claims in the Amended Complaint for strict liability, negligence, negligent misrepresentation/failure to warn, breach of express and implied warranties, and loss of consortium.

DISCUSSION

Defendants now seek to dismiss the Amended Complaint arguing that Plaintiffs' claims are preempted and that Plaintiffs have otherwise failed to state a claim. Defendants also seek judicial notice of the Food and Drug Association's ("FDA") pre-market approval of St. Jude's Durata lead and St. Jude's implantable cardioverter defibrillator. The Court will first address the applicable legal standard before turning to the substance of Defendants' motions.

I. Legal Standard

In deciding Rule 12(b)(6) motions to dismiss, the Court applies a "plausibility standard," which is guided by "[t]wo working principles." Ashcroft v. Iqbal, 556 U.S. 662, 678, 129 S. Ct. 1937, 173 L. Ed. 2d 868 (2009); accord Harris v. Mills, 572 F.3d 66, 71-72 (2d Cir. 2009). First, although the Court must accept all allegations as true, this "tenet" is "inapplicable to legal conclusions;" thus, "[t]hreadbare

recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." Iqbal, 556 U.S. at 678; accord Harris, 572 F.3d at 72. Second, only complaints that state a "plausible claim for relief" can survive a Rule 12(b)(6) motion to dismiss. Iqbal, 556 U.S. at 679. Determining whether a complaint does so is "a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." Id.; accord Harris, 572 F.3d at 72.

Furthermore, the Court is confined to "the allegations contained within the four corners of [the] complaint." Pani v. Empire Blue Cross Blue Shield, 152 F.3d 67, 71 (2d Cir. 1998). This has been interpreted broadly to include any document attached to the Complaint, any statements or documents incorporated in the Complaint by reference, any document on which the Complaint heavily relies, and anything of which judicial notice may be taken. See Chambers v. Time Warner, Inc., 282 F.3d 147, 152-53 (2d Cir. 2002) (citations omitted); Kramer v. Time Warner Inc., 937 F.2d 767, 773 (2d Cir. 1991).

II. Analysis

A. Preemption Under the MDA

In 1976, congress enacted the Medical Device Amendments ("MDA") to the Food, Drug, and Cosmetic Act ("FDCA"), giving the FDA the authority to regulate medical devices. See generally 21 U.S.C. § 360c et. seq. The MDA creates three

levels of scrutiny, depending on the type of medical device, before pre-market approval ("PMA") can be obtained. See Burkett v. Smith & Nephew Gmbh, No. 12-CV-4895, 2014 WL 1315315, at *1 (E.D.N.Y. Mar. 31, 2014) (citing 21 U.S.C. § 360c(a)(1)). So-called "Class III" medical devices are subject to the highest level of scrutiny. "The PMA process for a Class III medical device is a 'rigorous' process that typically requires submission of a multivolume application that includes reports of safety and efficacy studies, an explanation of the device's components, and details regarding its manufacturing, packaging, and installation." Id. (citing 21 U.S.C. § 360e; Riegel v. Medtronic, Inc., 552 U.S. 312, 317-18, 128 S. Ct. 999, 1004, 169 L. Ed. 2d 892 (2008)).

Even after receiving PMA, the manufacturer must comply with reporting and other obligations, including submission of an application for supplemental premarket approval to make any changes in the design specifications, manufacturing processes, or labeling of the medical device that would affect safety or effectiveness of the device. Id.

The MDA includes an express preemption provision, which provides:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to [medical devices covered by the MDA] any requirement--

> (1) which is different from, or in addition to, any requirement applicable under [the MDA] to the device, and
> (2) which relates to the safety or effectiveness of the device or any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a). The Supreme Court in Riegel shed some additional light on the "different from, or in addition to" language. Riegel, 552 U.S. at 329-30, 128 S. Ct. at 1011. Specifically, it held that "parallel" claims, are not preempted. In other words, "[t]he Court observed that the MDA preemption provision does not bar a state from providing a damages remedy for claims premised on the violation of FDA regulations, because 'the state duties in such a case parallel, rather than add to, federal requirements.'" Burkett, 2014 WL 1315315, at *2 (quoting Riegel, 552 U.S. at 330, 128 S. Ct. at 1011). Thus, to successfully circumvent preemption, a plaintiff must allege a claim based upon violation of an FDA regulation.

To complicate the preemption doctrine further, however, a plaintiff's claim cannot be based solely on that violation. The FDA regulations themselves do not provide a private cause of action. See Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 348, 349 n.4, 121 S. Ct. 1012, 148 L. Ed. 2d 854 (2001). Thus, "[t]o shoot this [narrow gap through which a plaintiff's state-law claim must fit to escape preemption], the 'plaintiff must be suing for conduct that violates [federal

law, or Section 360k(a) pre-empts the claim,] . . . but the plaintiff must not be suing because the conduct violates' federal law, because he has no private right to bring such a claim.'" Gale v. Smith & Nephew, Inc., --- F. Supp. 2d ----, 2013 WL 563403, at *3 (S.D.N.Y. Feb. 13, 2013) (quoting In re Medtronic, Inc. v. Sprint Fidelis Leads Prods. Liab. Litig., 623 F.3d 1200, 1204 (8th Cir. 2010) (emphases and alterations in original)). "Stated differently, 'section 360k protects a medical device manufacturer from liability to the extent that it has complied with federal law, but it does not extend protection from liability where the [state tort] claim is based on a violation of federal law.'" Id. (quoting Bausch v. Stryker Corp., 630 F.3d 546, 552 (7th Cir. 2010) (alteration in original)).

Finally, the plaintiff's claim must otherwise satisfy the general Iqbal/Twombly pleading standards, and "cannot simply make the conclusory allegation that defendant's conduct violated FDA regulations." Simon v. Smith & Nephew, Inc., --- F. Supp. 2d ----, 2013 WL 6244525, at *4 (S.D.N.Y. Dec. 3, 2013).

Defendants argue that Plaintiffs' claims are preempted and fail to state a parallel claim because the Amended Complaint does not identify the specific federal regulations violated or how they were violated. Defendants further argue that Plaintiffs' claims are also impliedly preempted and that

Plaintiffs have otherwise failed to state a claim for their breach of warranty, negligent misrepresentation, and loss of consortium claims. The Court will address each of these arguments in turn.

B. Judicial Notice

Before the Court can fully address preemption, however, the Court also notes that Defendants have moved for judicial notice of: (1) the FDA's PMA of St. Jude's Durata lead; and (2) the FDA's PMA of St. Jude's implantable cardioverter defibrillator. (See Defs.' Br. for Judicial Notice, Docket Entry 17.) In support, Defendants provide the FDA's PMA letters. (Defs.' Br. for Judicial Notice, Exs. 1-2.) Plaintiffs have not opposed this motion and the Court finds that judicial notice is appropriate here.

A court may judicially notice a fact when the fact(s) are "(1) generally known within the trial court's territorial jurisdiction; or (2) can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." FED. R. EVID. 201(b). Here, Defendants provide accurate documents from the FDA reflecting PMA for the devices at issue. Judicial notice of such facts is consistent with precedent. See, e.g., Gale, 2013 WL 563403, at *1 n.2; Desabio v. Howmedia Osteonics Corp., 817 F. Supp. 2d 197, 201 n.3 (W.D.N.Y. 2011); (Defs.' Br. for Judicial Notice at 2-3 (collecting cases)).

Accordingly, Defendants' motion for judicial notice is GRANTED.

C. Preemption & Claims

The Court thus turns to each of Plaintiffs' claims.

1. Strict Liability

Plaintiffs assert claims sounding in strict liability for design defect, manufacturing defect, and failure to warn. Specifically, they assert that

> the defibrillator and Durata lead in question was defective in that, among other things, it was made of improper and defective material; it was improperly designed; it was improperly manufactured; it failed to have adequate and proper warnings or instructions; it was not safe to be used for the purposes intended; it was inherently and/or unreasonably dangerous; its utilization violated FDA regulations; and it caused severe injuries while being used and the products were otherwise defective.

(Am. Compl. ¶ 50.)

a. Manufacturing Defect

Plaintiff alleges, among other things, that Defendants violated 21 U.S.C. § 351(h) by making unsanctioned adulterations to the Durata lead in violation of CGMPs and that the Durata lead and/or defibrillator had an impurity, imperfection, and/or other product defect. (Am. Compl. ¶¶ 54, 74.) They further allege that Defendants violated 21 C.F.R. § 820.75 "by failing to ensure that the process of manufacturing the Durata lead was

validated" and by failing to establish manufacturing procedures for monitoring the Durata lead, failing to establish procedures for control of process parameters, and failing to monitor the flow of the machinery. (Am. Compl. ¶¶ 56, 59-61.)

> Under New York law, "[t]o plead and prove a manufacturing flaw under either negligence or strict liability, the plaintiff must show that a specific product unit was defective as a result of some mishap in the manufacturing process itself, improper workmanship, or because defective materials were used in construction, and that the defect was the cause of plaintiff's injury."

Burkett, 2014 WL 1315315, at *4 (quoting Colon ex rel. Molina v. BIC USA, Inc., 199 F. Supp. 2d 53, 85 (S.D.N.Y. 2001)). Here, similar to the case of Burkett v. Smith & Nephew Gmbh, Plaintiffs use an FDA warning letter, which was issued subsequent to Mr. Franzese's operation, to argue "post[ ] PMA violation of federal law," and specifically, violation of the CGMPs. Certainly, the FDA warning letter, issued on January 10, 2013--almost three years after Mr. Franzese's operation--cites to various CGMP violations, including that the Durata lead was adulterated because methods were not in conformity with CGMPs. (See Dell Aff. ¶¶ 11-12 & Ex. D.)

However, the law is clear that Plaintiffs must identify a specific federal regulation allegedly violated. See Desabio, 817 F. Supp. 2d at 204 ("'To properly allege parallel

claims, the complaint must set forth facts[] pointing to specific PMA requirements that have been violated.'" (quoting Wolicki-Gables v. Arrow Int'l, Inc., 634 F.3d 1296, 1301 (11th Cir. 2011)). Here, Plaintiffs identity the CGMPs. Courts across the country are generally split on this issue. Compare Gelber v. Stryker Corp., 788 F. Supp. 2d 145, 159 (S.D.N.Y. 2011) (finding that manufacturing defect claims premised on CGMPs were not preempted) with Illaraza v. Medtronnic, Inc., 677 F. Supp. 2d 582, 588 (E.D.N.Y. 2009) and Horowitz v. Stryker Corp., 613 F. Supp. 2d 271, 283-84 (E.D.N.Y. 2009). Moreover, only the Sixth and Seventh Circuits have directly spoken on this issue, both finding that allegations founded on violations of CGMPs are sufficient to state a claim. See Howard v. Sulzer Orthopedics, 382 F. App'x 437 (6th Cir. 2010); Bausch v. Stryker Corp., 630 F.3d 546 (7th Cir. 2010). Despite this precedent, though, the Eastern District of New York has generally held that parallel claims may not be predicated on violation of CGMPs. See Burkett, 2014 WL 1315315, at *5; Ilarraza, 677 F. Supp. 2d at 588 ("The intentionally vague and open-ended nature of the [CGMP] regulations relied upon is the precise reason why they cannot serve as the basis for a parallel claim."). Contrary to Plaintiffs' argument that there has been a shift toward allowing such claims (Dell Aff. ¶ 26), Eastern District of New York precedent--including Burkett, which was issued just a few months

ago and after the parties briefed the current motion--has held that the CGMPs do not identify a federal law that is specific to the medical device at issue, thus forming an insufficient basis for a parallel claim. See Burkett, 2014 WL 1315315, at *5 ("Because Burkett's manufacturing defect claim is based on violation of generally applicable CGMPs, as opposed to federal requirements specific to the R3 liner, preemption bars the claim.").

Moreover, Plaintiffs do allege that the Durata lead was adulterated in violation of Section 501(h) of the FDCA and that the lead and/or defibrillator had an impurity, imperfection, or other product defect. (Am. Compl. ¶¶ 54, 74.) Even assuming that such allegations assert a sufficient violation of federal regulations, Plaintiffs have not sufficiently alleged how this violation caused Plaintiffs' injuries. Specifically, the Amended Complaint alleges that "Defendants violated federal law by making unsanctioned adulterations" to the Durata lead. (Am. Compl. ¶ 54.) However, such assertions appear to be based on the FDA warning letter, which simply stated that the Durata lead was considered adulterated within the meaning of Section 501(h) because "the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation" are not in conformity with CGMPs. (Dell Aff. ¶ 12(1) & Ex. D.) The

specific CGMPs identified, though, do not have any direct implications on how or why the Durata lead prematurely deteriorated.

Allegations regarding adulterations in particular can sufficiently state a claim where the violation of CGMPs also indicate a deviation from PMA requirements. In Purcel v. Advanced Bionics Corp., No. 07-CV-1777, 2008 WL 3874713 (N.D. Tex. Aug. 13, 2008), for example, the plaintiffs had sufficiently alleged a non-preempted claim where they asserted that the defendant, subsequent to PMA, changed its supplier, altered the device's mechanical configuration, and changed the length, composition, and "firing" process for glass used in the device. 2008 WL 3874713, at *1. The result was that moisture levels within the cochlear implants exceeded the maximums set out by the FDA, causing the device to malfunction. Id.; see also Ilarraza, 677 F. Supp. 2d at 589 (citing as examples Purcel and Rollins v. St. Jude Medical, 583 F. Supp. 2d 790 (W.D. La. 2008), in which "the plaintiff stated a parallel claim where he was able to point to the alleged violation of premarketing packaging requirements applicable to the particular medical device at issue").

Contrary to cases such as Purcel, Plaintiffs have failed to connect a violation of the CGMPs with the violation of any federal regulation specific to the devices at issue or

explain how such violations caused Mr. Franzese's injury. Formulaic recitation is insufficient. See Ilarraza, 677 F. Supp. 2d at 588-89. This is true, even though courts have recognized that PMA documents are often confidential, making it difficult for a plaintiff to plead the exact violation. See Burgos v. Satiety, Inc., No. 10-CV-2680, 2011 WL 1327684, at *3-4 (E.D.N.Y. Apr. 5, 2011). Nonetheless, alleging that a device was adulterated, without explaining how that adulteration contravened federal law specific to the device fails to state a claim. Gale, 2013 WL 563403, at *3.

Accordingly, Plaintiffs' claim for strict liability-manufacturing defect is preempted and otherwise fails to state a claim.

b. Design Defect

Next, Plaintiffs allege a claim under strict liability for design defect. They allege, inter alia, that Defendants violated various CGMPs by failing to establish and maintain adequate procedures for verifying the design of the Durata lead; failing to validate the test methods implemented during the Durata lead design verification testing; implementing test methods that did not follow a national standard; failing to follow established test procedures; and performing design verification of the Durata lead prior to it establishing design inputs. (Am. Compl. ¶¶ 62-69.)

"'Under New York law, 'a design defect may be actionable under a strict products liability theory if the product is not reasonably safe.'" Burkett, 2014 WL 1315315, at *4 (quoting Denny v. Ford Motor Co., 87 N.Y.2d 248, 256-57, 639 N.Y.S.2d 250, 662 N.E.2d 730 (1995)); see also Bertini v. Smith & Nephew, Inc., --- F. Supp. 2d ----, 2014 WL 1028950, at *5 (E.D.N.Y. Mar. 17, 2014) (listing the relevant factors as "the product as designed posed a substantial likelihood of harm," "it was feasible to design the product in a safer manner," and "the defective design was a substantial factor in causing plaintiff's injury" (internal quotation marks and citation omitted)). "'[A] defectively designed product is one which, at the time it leaves the seller's hands, is in a condition not reasonably contemplated by the ultimate consumer and is unreasonably dangerous for its intended use . . . .'" Burkett, 2014 WL 1315315, at *4 (quoting Robinson v. Reed-Prentice Div. of Package Mach. Co., 49 N.Y.2d 471, 479, 426 N.Y.S.2d 717, 403 N.E. 2d 400 (1980)).

Again, similar to the claims in Burkett, Plaintiffs assert that Defendants failed to comply with federal law in designing the Durata lead after its PMA approval. (See Am. Compl. ¶¶ 62-69.) In Burkett, as here, Plaintiffs point to an FDA warning letter relating primarily to manufacturing issues, and have not alleged that Defendants strayed from the design

approved by the FDA. See 2014 WL 1315315, at *4. Accordingly, this claim is preempted. See Bertini, 2014 WL 1028950, at *6 (finding strict liability design defect claim preempted where the plaintiffs did not allege that the design failed to meet the FDA requirements, but rather that the device could have been designed safer); Simon, 2013 WL 6244525, at *7 ("[D]esign defect claims regarding a PMA-approved device are squarely preempted by the MDA.").

c. Failure to Warn

Next, Plaintiffs assert a claim for strict liability based upon Defendants' alleged failure to warn. Specifically, they assert that Defendants violated 21 U.S.C. § 352(t)(2) by misbranding the Durata lead and/or refusing or failing to furnish material or information and by failing to report to the FDA no later than thirty days after receipt of information that the Durata lead malfunctioned.

To prevail on this claim, Plaintiffs must "'demonstrate that (1) a manufacturer has a duty to warn (2) against dangers resulting from foreseeable uses about which it knew or should have known, and (3) that failure to do so was the proximate cause of the harm.'" Burkett, 2014 WL 1315315, at *6 (quoting State Farm Fire & Cas. Co. v. Nutone, Inc., 426 F. App'x 8, 10 (2d Cir. 2011)). Plaintiffs' allegations cite to 21 U.S.C. § 352(t)(2), following the assertions in the FDA warning

letter, that the Durata lead was misbranded and that Defendants failed to report to the FDA no later than 30 calendar days after receipt of information that the Durata lead malfunctioned. (Am. Compl. ¶¶ 70-71.) The FDA warning letter was issued nearly three years after Mr. Franzese's initial surgery. Plaintiffs have not alleged how any shortcomings identified in a 2013 letter relate to the state of affairs in 2010. Thus, Plaintiffs have specifically failed to allege proximate cause. Accordingly, even if Plaintiffs' claim for failure to warn is not preempted, they have otherwise failed to state a claim in this regard.

2. Breach of Warranty (Express and Implied)

Plaintiffs also assert claims for breach of express warranty and breach of implied warranty. They allege that Mr. Franzese and his treating doctors relied on Defendants' express representations set forth in the defibrillator and lead's packaging materials and on an implied warranty that the products were safe and merchantable. (Am. Compl. ¶¶ 102-04.) In addition, they assert that Defendants' representatives made personal representations to Mr. Franzese and/or his doctors that the devices were safe, long lasting, would not prematurely erode, and would not require any additional surgical intervention. (Am. Compl. ¶¶ 108-09.)

"Under New York law, '[t]o state a claim for breach of express warranty, the plaintiff must show that there was an affirmation of fact or promise by the seller, the natural tendency of which [was] to induce the buyer to purchase, and that the warranty was relied upon.'" Burkett, 2014 WL 1315315, at *8 (quoting Gelber, 788 F. Supp. 2d at 165 (alterations in original)). To state a claim for breach of implied warranty, Plaintiffs must sufficiently allege "'that the [product] was not reasonably fit for the ordinary purpose for which it was intended.'" Id. (quoting Horowitz, 613 F. Supp. 2d at 284 (alteration in original)).

To the extent that Plaintiffs' claims rest on the packaging materials, which were approved by the FDA, it is preempted. See id. To the extent that Plaintiffs allege that representatives made specific representations beyond those contained in the packaging materials, Plaintiffs fail to state a claim. Plaintiffs make only a conclusory allegation without providing any factual support for the context of any such alleged representations. See Horowitz, 613 F. Supp. 2d at 286 ("Without sufficient allegations identifying the conduct at issue, plaintiff has failed to give the defendants notice of the grounds of her claim.").

Moreover, "Plaintiffs must show [Defendants'] product 'was not minimally safe for its expected purpose' to maintain

their breach of implied warranty claim." Bertini, 2014 WL 1028950, at *11 (quoting Caronia v. Philip Morris USA, Inc., 715 F.3d 417, 434 (2d Cir. 2013)). However, "[u]nder the MDA, plaintiffs cannot demand that defendant design the [medical device] in a safer manner, when the FDA has already approved the safety and effectiveness of defendant's design." Id. The FDA warning letter does not save this claim. Though the letter identifies potential issues, it does not equate to a finding that the devices were unsafe or unfit for their ordinary purpose. See Horowitz, 613 F. Supp. 2d at 284 ("The FDA warning letters never imply, and plaintiff never alleges, that defendants' federal violations caused the Trident System to be unfit in assisting patients in walking, which is the purpose for which the Trident System was created.").

3. Negligence

Plaintiffs also assert a claim for negligence. (See Am. Compl. ¶ 86 ("Defendants breached their duties in that they failed to exercise reasonable care in the design, testing, manufacture, packaging, labeling, warnings, quality assurance, marketing, p[o]st-market monitoring and/or surveillance, advertising, promotion, distribution and sale of the Plaintiff's implantable defibrillator and Durata lead."); see also Am. Compl. ¶ 87.)

To state a claim for negligence,

> a plaintiff must show "(1) that the manufacturer owed plaintiff a duty to exercise reasonable care; (2) a breach of that duty by failure to use reasonable care so that a product is rendered defective, i.e. reasonably certain to be dangerous; (3) that the defect was the proximate cause of the plaintiff's injury; and (4) loss or damage."

Burkett, 2014 WL 1315315, at *7 (quoting Colon ex rel. Molina, 199 F. Supp. 2d at 82)).

To the extent that Plaintiffs base their negligence claims on design defect, manufacturing defect, or failure to warn, these claims are preempted or otherwise fail to state a claim, and therefore Plaintiffs' negligence claim fails for the same reason. See id.; Bertini, 2014 WL 1028950, at *10.

4. Negligent Misrepresentation

Plaintiffs allege negligent misrepresentation because they assert that Defendants misbranded the Durata lead and/or failed to furnish material or information respecting the device as required, in violation of 21 U.S.C. § 352(t)(2). (Am. Compl. ¶ 94.) They further assert that "Defendants were negligent in that they did not disclose manufacturing flaws to the FDA or treating doctors although said manufacturing flaws increased risk of injury to patients receiving the Promote Plus ICD and/or the Durata lead." (Am. Compl. ¶ 95.)

Negligent misrepresentation claims are subject to the heightened pleading standard set forth by Federal Rule of Civil

Procedure 9. See Burkett, 2014 WL 1315315, at *7. Accordingly, Plaintiffs must allege "'(1) what the omissions were (2) the person responsible for the failure to disclose; (3) the context of the omissions and the manner in which they misled the plaintiff; and (4) what the defendant obtained through the fraud.'" Id. (quoting Woods v. Maytag Co., 807 F. Supp. 2d 112, 119 (E.D.N.Y. 2011)).

Plaintiffs have not done so here. "[T]he mere fact that [Mr. Franzese] purchased the [Durata lead and defibrillator] does not show that [Mr. Franzese] or his physician[s] actually relied on defendant[s'] alleged misrepresentations and omissions when deciding whether to proceed with [Mr. Franzese's] surgery." Bertini, 2014 WL 1028950, at *10.

Accordingly, Plaintiffs have failed to state a claim for negligent misrepresentation.

5. Loss of Consortium

Finally, Mrs. Franzese's loss of consortium claim is a derivative claim, which does not exist independently of Mr. Franzese's claims. See id. at *12. Given that his claims fail, so must the loss of consortium claim as well.

CONCLUSION

For the foregoing reasons, Defendants' motions to dismiss and for judicial notice are both GRANTED. As Plaintiffs

have already attempted to amend their Complaint, and such amendment being unsuccessful, the Court finds that further amendment would be futile.

Accordingly, the Clerk of the Court is directed to mark this matter CLOSED.

SO ORDERED.

/s/ JOANNA SEYBERT
Joanna Seybert, U.S.D.J.

Dated: June 23, 2014
Central Islip, NY